K081583

Date: June 03, 2008

510(k) Summary

JUL 28 2008

3-1. 510(k) owner (submitter)

1) Name	KURARAY MEDICAL INC.
2) Address	1621 Sakazu, Kurashiki, Okayama 710-0801, Japan
3) Contact person	Michio Takigawa Quality Assurance Department
4) Contact person in U.S.	Koji Nishida KURARAY AMERICA INC. 600 Lexington Avenue, 26th Floor New York, NY 10022 Tel: (212)-986-2230 (Ext. 115) or (800)-879-1676 Fax: (212)-867-3543

3-2. Name of Device

1) Trade / Proprietary name	CLEARFIL SA CEMENT
2) Classification name	Dental cement (21 CFR section 872.3275. Product code: EMA)
3) Common name	Dental adhesive resin cement

3-3. Predicate device

1) PANAVIA F 2.0	510(k) Number:	K032455
	Product Code:	EMA
	21 CFR Section:	872.3275
	Applicant:	KURARAY MEDICAL INC.
2) CLEARFIL ESTHETIC CEMENT & DC BOND	510(k) Number:	K062410
	Product Code:	EMA
	21 CFR Section:	872. 3275
	Applicant:	KURARAY MEDICAL INC.
3) MAXCEM	510(k) Number:	K041474
	Product Code:	EMA
	21 CFR Section:	872. 3275
	Applicant:	SYBRON DENTAL SPECIALTIES INC.

3-4. Device Description

1) CLEARFIL SA CEMENT is a dual-cure (light-and/or self-cure), self-adhesive resin cement for conventional porcelain, ceramic, hybrid ceramics (e.g. ESTENIA C&B), composite resin and metal restorations.

2) It is classified into dental cement (21 CFR section 872.3275, Product code: EMA) according to 21 CFR § 872 since it is composed of various materials other than zinc oxide-eugenol.

3) According to the applicable FDA recognized consensus standard, ISO 4049: 2000 "Dentistry - Polymer-based filling, restorative and luting materials", this device is classified into the following:

- Class 3: materials that are cured by the application of external energy and also have a self-curing mechanism present

3-5. Substantial Equivalence Discussion

1) Intended uses

It is intended to be used for the indications listed in the left hand column of the table of "Section 5: Executive Summary, Table 5" that are equivalent to the predicate devices, PANAVIA F2.0 and CLEARFIL ESTHETIC CEMENT & DC BOND.

2) Chemical ingredients / Safety

All the chemical ingredients of CLEARFIL SA CEMENT, the subject device, have been used in the predicate devices, PANAVIA F2.0 and CLEARFIL ESTHETIC CEMENT & DC BOND. It indicates that the safety of the applicant device is substantially equivalent to that of the predicate devices.

3) Effectiveness / Performance

CLEARFIL SA CEMENT, the subject device, has been verified to comply with the requirements of the applicable FDA recognized consensus standard, ISO 4049: 2000 "Dentistry - Polymer-based filling, restorative and luting materials". As to comparison with the predicate device, MAXCEM, according to ISO 4049: 2000, it was proved that both the subject one and the predicate one complied with ISO 4049: 2000 and the subject one should be effective as well as the predicate one.

3-6. Biocompatibility

All the chemical ingredients of CLEARFIL SA CEMENT, the subject device, have been used in the predicate devices as shown on the tables of "Section 7: Substantial Equivalence Discussion, Table: 7-2, 7-3, 7-4" where all the chemical ingredients of the subject device are listed in the left hand column and the abbreviated names of the predicate devices which contain the chemical component are listed in the right hand. From those tables, it can be said that the safety of the subject device is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 8 2008

Kuraray Medical, Incorporated
C/O Mr. Koji Nishida
General Manager
Kuraray America, Incorporated
600 Lexington Avenue, 26th Floor
New York, New York 10022

Re: K081583
Trade/Device Name: CLEARFIL™ SA CEMENT
Regulation Number: 872.3275
Regulation Name: Dental Cement
Regulatory Class: II
Product Code: EMA, KLE
Dated: June 3, 2008
Received: June 12, 2008

Dear Mr. Nishida:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K081583

Device Name: CLEARFIL SA CEMENT

Indications for Use:

1) Cementation of crowns, bridges, inlays and onlays made of conventional porcelain, ceramic, hybrid ceramics, composite resin or metal
2) Cementation of metal cores, resin cores, metal posts or glass-fiber posts

Prescription Use ✓ AND/OR Over-The-Counter Use N/A

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

Division Sign-Off)
Division of Anesthesiology, General Hospital
nfection Control, Dental Devices

10(k) Number: K081583